IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

Kathryn Kiker, et al., Plaintiffs, vs. SmithKline Beecham Corporation d/b/a GlaxoSmithKline LLC, Defendant.	:	Case No. 2:14-cv-02164-EAS-TPK Chief Judge Edmund A. Sargus, Jr. Magistrate Judge Terence P. Kemp

DEFENDANT GLAXOSMITHKLINE LLC'S MOTION *IN LIMINE*
TO EXCLUDE PLAINTIFFS' ALLEGATIONS ABOUT OUTSIDE COUNSEL
(ORAL ARGUMENT REQUESTED)

Defendant GlaxoSmithKline LLC ("GSK") moves this Court *in limine* for an Order excluding allegations about outside counsel because that evidence is unreliable, irrelevant, and inadmissible hearsay.

I. INTRODUCTION

In pre-trial motions in *Kilker v. GSK*, the first Paxil pregnancy case tried in the Philadelphia Mass Tort Program ("Philadelphia MTP") in 2009, plaintiffs wrongly suggested that GSK's outside counsel at Phillips Lytle LLC, Tamar Halpern, sought to manufacture scientific evidence about Paxil to help GSK defend itself in lawsuits. (*See Kilker v. GSK,* Feb. Term 2007, Case No. 1813 (Phila. Ct. Com. Pl.) Mot. Hr'g Tr., Sept. 3, 2009 at 105:4-112:19 (excerpts attached as Ex. 1).)[1] The plaintiffs' pretext for this attack consisted of two brief e-mails sent by Dr. Gideon Koren, an independent outside researcher, to GSK in 2006. Dr. Koren requested access to certain data possessed by GSK that he thought would be helpful to a meta-

[1] For the convenience of the Court, exhibits are attached to the Declaration of William D. Kloss, Jr., accompanying this Motion.

analysis that his independent research group wished to undertake. He alluded to Attorney Halpern as the person who "requested" that he contact GSK directly. According to the plaintiffs, these e-mails somehow gave rise to an inference that Attorney Halpern created, manipulated, and/or ghost wrote the article Dr. Koren (and seven other independent scientists) ultimately published with the results of their meta-analysis in 2007. There is no support for this staggering leap of the imagination in the e-mails themselves or anywhere else. Even worse, plaintiffs' "interpretation" is flatly contradicted by undisputed facts in the record.

The *Kilker* court properly excluded the e-mails as inadmissible hearsay and barred the plaintiffs from making any argument about Attorney Halpern absent any additional evidence to support their unfounded allegations.[2] (*See Kilker v. GSK* Trial Tr., Sept. 14, 2009 p.m. at 33:15-36:25 (Ex. 5).) Nonetheless, Plaintiffs continue to assert these baseless and inflammatory allegations in this case. (Plts.' Opp'n to Def.'s Mot. for Summ. J. at 2-4 (Doc. 115); *see also, e.g.*, Plts.' Exhibit List, Jan. 17, 2017 (Doc. 159), Ex. Nos. 382, 387, 649, 1288, 4232, 4573-74.) GSK seeks the same ruling as in *Kilker*[3] because there is no basis for admitting this evidence in this case for the reasons set out below.

[2] Other courts have likewise rejected attempts by plaintiffs to make the same spurious allegations against Attorney Halpern. (*See Correa v. SmithKline Beecham Corp*. Hr'g Tr., Dec. 1, 2009 at 28:25-29:1 (quashing notice to depose Ms. Halpern on these issues and denying motion to disqualify her based on same allegations) (excerpts attached as Ex. 2); Aug. 14, 2008 Special Master's Report on Discovery Issues Argued on August 4, 2008 in *Steele v. GSK* at 5 (rejecting plaintiffs' efforts to depose Ms. Halpern on these issues) (finding vacated, along with all the other discovery orders in that case, after the case resolved.) (Ex. 3); *Hayes v. GSK* Hr'g Tr., Apr. 29, 2009 at 3:1-4:20 (granting GSK's protective order, ending efforts to depose Ms. Halpern) (excerpts attached as Ex. 4).)

[3] A ruling on a similar motion in the second Philadelphia MTP Paxil Pregnancy trial, *Blyth v. GSK*, was deferred when plaintiffs agreed not to oppose the motions before trial, and the evidence at issue was never offered. (*See Blyth v. GSK*, Sept. Term 2007, No. 3305 (Phila. Ct. Com. Pl.) Nov. 9, 2010 Order at Control No. 10030196 No. 7 (Ex. 6) (deferring GSK's similar motion *in limine)*.) In the most recent Paxil Pregnancy case to go to trial in the Philadelphia MTP, *Rader v. GSK*, plaintiffs agreed to defer the GSK's motion *in limine* on this issue and not present such evidence before approaching the court. (*See Rader v. GSK*, Sept. Term 2011, No. 3672 (Phila. Ct. Com. Pl.) Mar. 1, 2016 Ltr. from A. Ringstad to Judge New (Ex. 7).)

II. ARGUMENT

A. Plaintiffs' Only "Evidence" For Their Allegations is Inadmissible Hearsay.

Plaintiffs' sole "evidence" in support of their "attorney manipulation" theory consists of two e-mails from Dr. Koren, of the Motherisk group in Toronto, to GSK scientists. The first e-mail, to David Carpenter of GSK, reads:

> Dear David, ***I am contacting you at the request of Ms. Halperin's [sic] office in Buffalo.*** We are meta analyzing paxil in pregnancy, and the studies GSK has in house are critical, especially as we feel there is a potential publication bias in the published studies. I left a message for you on your phone with no response. Please contact me at your earlier [sic] convenience so I can share with you our design and approach. Many thanks GK.

(Aug. 11, 2006 E-mail from Gideon Koren to David Carpenter) (Ex. 8).) The second e-mail, three months later, responds to GSK epidemiologist Sara Ephross, who had previously told Dr. Koren to contact individual research groups directly if he wanted information:

> Dear Sara, as you must know, I cannot approach the different GSK researchers as I do not know who they are and their contacts. ***I want to remind you that our initiative was in response to request BY your legal experts, yet, it feels as if we cannot get much.*** I do not know if this reflects reluctance to share data, indifference, or just a very inefficient system. Unless we get from you data promptly, we will go ahead with our analysis and mention in the manuscript that attempts to receive data from GSK have failed. GK.

(Nov. 14, 2006 E-mail from Gideon Koren to Sara Ephross) (Ex. 9).) From the highlighted portions of these two messages alone, Plaintiffs want to draw an inference that Attorney Halpern recruited Dr. Koren to create a fraudulent study that would whitewash evidence of an association between Paxil and heart defects. (Plts.' Opp'n to Def.'s Mot. for Summ. J. at 4 (alleging that "[b]y 2006, GSK began manipulating scientific literature in order to defend itself in Paxil birth defect litigation.") (Doc. 115).)

In *Kilker*, the trial court held that these e-mails were inadmissible hearsay. (*See* Ex. 5, *Kilker v. GSK* Trial Tr., Sept. 14, 2009 at 33:15-36:25.) There can be no purpose to Plaintiffs

offering these e-mails in evidence except to attempt to prove that Attorney Halpern encouraged or instructed Dr. Koren to contact GSK and that she somehow "initiated" the meta-analysis. To do so, Plaintiffs must overcome two layers of hearsay. The first layer is Attorney Halpern's alleged out-of-court statement to Dr. Koren. As the e-mail reflects, Dr. Koren is allegedly stating or paraphrasing what someone else (Attorney Halpern) supposedly told him. The second layer of hearsay is, of course, the documents themselves. Hearsay within hearsay is patently inadmissible. Fed. R. Evid. 802, 805.

As the *Kilker* court held, the e-mails are not admissible under any hearsay exception. (*See* Ex. 5, *Kilker v. GSK* Trial Tr., Sept. 14, 2009 at 33:15-36:25.) They do not meet the requirements for admission of records of regularly conducted business under the Federal Rule of Evidence 803(6), which allows the admission of:

> A record of an act, event, condition, opinion, or diagnosis if: (A) the record was made at or near the time by--or from information transmitted by--someone with knowledge; (B) the record was kept in the course of a regularly conducted activity of a business, organization, occupation, or calling, whether or not for profit; (C) making the record was a regular practice of that activity; (D) all these conditions are shown by the testimony of the custodian or another qualified witness, or by a certification that complies with Rule 902(11) or (12) or with a statute permitting certification; and (E) the opponent does not show that the source of information or the method or circumstances of preparation indicate a lack of trustworthiness.

The e-mails at issue are nothing more than irregular, sporadic, and informal efforts by a third-party to request information from GSK. They are not records or reports that GSK kept in the course of a regularly conducted business activity. Their purpose plainly was not to record any alleged request made by Attorney Halpern, but to seek data from GSK. Based on the date of Attorney Halpern's only meeting with Dr. Koren — July 10, 2006 — neither e-mail was sent anywhere near the time Attorney Halpern allegedly made the request. (*See* Sept. 8, 2009 T. Halpern Aff. in *Kilker v. GSK* (Ex. 10); Sept. 8, 2009 M. Harris Aff. in *Kilker v. GSK* (Ex. 11).)

Further, there is no evidence that it was the regular practice of Dr. Koren's "business" to send e-mails like these. *See New York v. Microsoft Corp.*, Civil Action No. 98-1233, 2002 U.S. Dist. LEXIS 7683, at *8-9 (D.D.C. Apr. 12, 2002) (excluding e-mails that may have been "kept in the course of business" absent a showing that it was the "regular practice" of employees to write and maintain such e-mails).

Moreover, no one at GSK can make the foundational showing required under Fed. R. Evid. 803(6) because the statements at issue were made by Dr. Koren. As a prerequisite to admissibility, a custodian, or other qualified witness possessing knowledge regarding the creation or maintenance of such records, must attest that the proffered document meets the conditions established in 803(6). *See Cobbins v. Tennessee Dep't of Transp.,* 566 F.3d 582, 588 (6th Cir. 2009). Indeed, the only person who possibly could offer evidence that the e-mails meet any requirements of Fed. R. Evid. 803(6) is Dr. Koren himself. *Id.*

The circumstances surrounding the e-mails themselves also indicate a lack of trustworthiness, mandating their exclusion. "The business records exception is based on the indicia of reliability that attaches to a record created or maintained by an employer in the ordinary or regular course of business." *Cobbins,* 566 F.3d at 588. The reliability of records created or maintained in the regular course of business is supported by regularity and continuity, which breed "habits of precision," by actual experience in relying on the documents or by the duty to make an accurate record as part of a continuing job or occupation, and an entity's independent motivation in creating and relying on the document in the first instance. *See Id.*; *see also* Fed. R. Evid. 803, Adv. Note (6). These e-mails do not fit under that umbrella because they utterly lack the indicia of accuracy required under federal law. *See Cobbins*, 566 F.3d at 588 ("A business record is admissible under Rule 803(6) [only] where a sufficient foundation for

reliability is established."). The e-mails are obviously informal and sloppily constructed, as evidenced by the fact that Dr. Koren misspelled Attorney Halpern's name in the first e-mail and apparently had forgotten it altogether by the time he wrote the second e-mail. Further, contrary to any suggestion of untoward collusion between Dr. Koren and GSK, Dr. Koren even went so far as to threaten GSK with negative statements if the data were not produced to him. (*See* Ex. 9, Nov. 14, 2006 E-mail: "Unless we get from you data promptly, we will go ahead with our analysis and mention in the manuscript that attempts to receive data from GSK have failed.") In short, the very nature and content of the communications belie any inference of reliability.

B. The Evidence Does Not Support Any Inference of Wrongdoing by Attorney Halpern or GSK.

Even if Plaintiffs had admissible evidence that Attorney Halpern asked Dr. Koren to contact GSK to obtain data to be used in his planned meta-analysis — which they do not — there is no basis for then inferring that the request was part of a nefarious plot to manipulate data to publish inaccurate information in scientific journals about the risks of Paxil use by pregnant women. For over half a century, federal courts have found that when the available evidence does not make one possible inference any more reasonable than another, choosing between them is mere speculation. *See, e.g.*, *Wratchford v. S.J. Groves & Sons Co*., 405 F.2d 1061, 1066 (4th Cir. 1969) (explaining that although "it is the province of the jury to resolve conflicting inferences […p]ermissible inferences must still be within the range of reasonable probability, however, and it is the duty of the court to withdraw the case from the jury when the necessary inference is so tenuous that it rests merely upon speculation and conjecture."). Nothing in the e-mails supports the inference that Attorney Halpern or GSK initiated, influenced, or were otherwise involved with Dr. Koren's meta-analysis.

And additional evidence proves that Plaintiffs' speculation is wrong. The record contains

more about GSK's response to Dr. Koren and the study he and his co-authors ultimately produced — including the study itself. This evidence defeats any suggestion of collusion between Dr. Koren and GSK. For example, Dr. Ephross — the GSK scientist who responded to Dr. Koren's data request — testified in two depositions that: (1) GSK had nothing to do with Dr. Koren's decision to undertake his meta-analysis; (2) GSK did not provide Dr. Koren with any data or collaborate with him in any way; and (3) GSK, which was already searching for an outside investigator to conduct a meta-analysis, elected ***not*** to work with Dr. Koren because of doubts about his scientific rigor, and instead collaborated with a team from the University of North Carolina. (Apr. 23, 2009 Dep. of Sara Ephross in *Hayes v. GSK* at 167:24-168:5-12 (Ex. 12) (testifying that GSK "decided not to even approach Dr. Koren about potentially collaborating on the meta-analysis that they already had in progress"); June 10, 2009 Dep. of Sara Ephross in *In Re Paxil Pregnancy Cases* at 428:4-22 (Ex. 13) (stating that Dr. Koren's meta-analysis was "something he did on his own" and GSK "did not collaborate with him in any way").) She also testified that she was not aware of any involvement by Attorney Halpern in this process. (*See* Ex. 12, Apr. 23, 2009 Dep. of S. Ephross at 167:9-12.)

Further, the study Dr. Koren and his seven co-authors completed and published offers no evidence or inference of collusion. As a threshold matter, the authors make it very clear in the article itself that GSK had no involvement in creating it. They not only list several pharmaceutical companies ***other than GSK*** that provided research, but the eight authors specifically disclaim any involvement by GSK, noting that "none of the support has been related to paroxetine or any other SSRI." (*See* Bar-Oz, B., *et al.*, *Paroxetine and Congenital Malformations: Meta-Analysis and Consideration of Potential Confounding Factors*, CLINICAL THERAPEUTICS, 29:5 at 925 (2007) (Ex. 14).) And yet, Plaintiffs apparently would have the

Court infer that the statement that GSK was not involved means precisely the opposite.

The ultimate conclusions reached by Dr. Koren and his co-authors also belie any suggestion that the study was "ghost written" or "manipulated" for GSK. Among other findings, the authors concluded that if all cardiac defects are "lumped" together — a methodology with which GSK takes issue — the use of Paxil in the first trimester of pregnancy is "associated with a significant increase in the risk for cardiac malformation." (*Id.* at 918.) It simply makes no sense to infer that Attorney Halpern's alleged contacts had a wrongful motive when Plaintiffs can point to no wrongful result that might have been advantageous to GSK.

Finally, the sworn statements of Attorney Halpern and that of her partner Martha Harris confirms that there was nothing improper about her contacts with Dr. Koren. The two partners met with him once, on July 10, 2006 in Toronto, to discuss the possibility of him serving as an expert witness for GSK. (*See* Ex. 10, Halpern Aff. ¶¶ 2, 5.) At that meeting, he told Attorneys Halpern and Harris that he had decided on his own to conduct a meta-analysis of selective serotonin reuptake inhibitors (SSRIs) and birth defects, which would include Paxil. (*Id.* ¶ 9.) He also asked Attorney Halpern if she could provide him additional data from GSK for his study, but she told him that any such request had to be made directly to GSK because she had no access to or authority to provide him any such data. (*Id.* ¶ 10.) That was the only discussion they had about the study. (*Id.* ¶¶ 10, 12, 15.) Attorney Harris fully corroborates Attorney Halpern's account. (*See* Ex. 11, Harris Aff. ¶¶ 2-6.) Attorneys Halpern and Harris decided not to retain Dr. Koren as an expert for GSK, and neither lawyer has spoken to him since. (*See* Ex. 10, Halpern Aff. ¶ 15.) Given these additional facts, it is clear that Plaintiffs have no basis to argue that the e-mails suggest improper intervention by GSK's counsel.

C. Plaintiffs' False and Baseless Allegations Are Irrelevant to the Facts of this Case.

Even if they were not completely false (which they are), Plaintiffs' allegations of "attorney misconduct" would be inadmissible here because they are irrelevant to the issues at hand. Both of Dr. Koren's e-mails to GSK employees were sent in late 2006, ***six years after*** C.S. was conceived, and ***after*** Paxil's labeling was changed to reclassify the medication as Pregnancy Category D. Dr. Koren's supposedly "tainted" article was not even accepted for publication until March of 2007. Thus, even accepting all of Plaintiffs' conjecture as true (which is not appropriate), none of the conduct they allege could have impacted Plaintiffs' alleged injuries. These allegations therefore have no possible relevance to this matter.

Plaintiffs may argue that they somehow are raising this issue for some other purpose, but those efforts also should be unavailing. Under federal law, otherwise relevant evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice. Under Rule 403, a court has broad discretion to exclude even relevant evidence "if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusion of the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403; *United States v. Vance*, 871 F.2d 572, 576 (6th Cir. 1989). When evidence's probative value, if any, is substantially outweighed by the risk of unfair prejudice, it should be excluded. *United States v. Gibbs*, 797 F.3d 416, 422 (6th Cir. 2015). Evidence is unfairly prejudicial if it "tends to lead jurors to make a decision on an improper basis." *United States v. Ford*, 761 F.3d 641, 648 (6th Cir. 2014). The probity of whatever ancillary point Plaintiffs hope to make surely would be outweighed not only by the risk of unfair prejudice to GSK, but also by the potential damage to the reputation of its attorney based on irresponsible speculation. *See*

United States v. Wilson, 586 F. Supp. 1011, 1016 (S.D.N.Y. 1983) (excluding evidence of controversial acts by nonparties as "utterly irrelevant" and a waste of time).

D. Baseless Allegations Against An Attorney Adversary Have No Place in Litigation.

Despite the lack of any evidence, admissible or otherwise, to support their unfounded and irrelevant allegations against Attorney Halpern, plaintiffs' counsel in another case, *Hayes v. GSK*, used these allegations in an attempt to intimidate Attorney Halpern during the deposition of one of the plaintiffs' experts, Dr. Anick Bérard. (*See* Apr. 7, 2009 Dep. of Anick Bérard in *Hayes v. GSK* at 169:2-6, 341:11-16) (excerpts attached as Ex. 15).)

Not surprisingly, the United States Supreme Court and other federal courts have not looked with favor upon these kinds of attacks. *See* e.g., *United States v. Young*, 470 U.S. 1, 9 (1985) (observing that "inflammatory attacks on the opposing advocate" have "no place in the administration of justice and should neither be permitted nor rewarded; a trial judge should deal promptly with any breach [of this rule] by either counsel"); *Nault's Auto. Sales, Inc. v. Am. Honda Motor Co., Inc.*, 148 F.R.D. 25, 34 & 37 (D.N.H. 1993) (striking offensive pleadings and sanctioning an attorney for leveling spurious charges against opposing counsel). Nor has the Ohio Supreme Court looked favorably on these types of attacks. *See e.g., Disciplinary Counsel v. Stafford*, 965 N.E.2d 971 (Ohio 2012) (suspending an attorney for one year, in part, because he made false allegations of judicial impropriety against a sitting judge in a court filing without taking any action to verify the truth of the statements and did not withdraw them after the falsity of the statements had been exposed).

The inference Plaintiffs will attempt to draw if this evidence is not excluded lacks any support, is refuted by all the existing evidence, and has no probative value as to any of Plaintiffs' claims. These reckless allegations against another attorney have no relevance to whether GSK's

actions caused injury to Plaintiffs. Instead, Plaintiffs' effort to push this issue serves only two purposes: to distract the jury with unsupported allegations of misconduct, or to apply pressure to GSK by threatening the hard-earned reputation of its longtime counsel. Neither is legitimate.

III. CONCLUSION

For the reasons stated above, the Court should exclude Plaintiffs' allegations about outside counsel, Dr. Koren's e-mails to GSK employees, and "lawyer involvement in science."

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CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing was served upon all counsel of record, this 24th day of January, 2017, by the Court's electronic service.

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ORDER

AND NOW, this ____ day of _____, 2017, upon consideration of the Motion *in Limine* to Exclude Plaintiffs' Allegations About Outside Counsel filed by Defendant GlaxoSmithKline LLC ("GSK"), and any response thereto, and having considered the arguments of counsel, it is hereby ORDERED that Defendant's Motion is GRANTED. Any reference to, or allegations regarding, GSK's outside counsel is hereby EXCLUDED.

_____ _____

Date

Edmund A. Sargus, Jr.
Chief United States District Judge